NOT FOR PUBLICATION (Docket No. 21)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

LISA M. BANNER and PHILLIP SHAUN BANNER,	:	
Plaintiffs,	:	Civil No. 08-0741 (RBK/KMW)
v.	:	**OPINION**
CYBERONICS, INC.,	:	
Defendant.	:	

KUGLER, United States District Judge:

This matter arises out of an allegedly defective Class III medical device, the Vagus Nerve Stimulation (VNS) Therapy System. Plaintiffs Lisa M. Banner and Phillip Shaun Banner have asserted five state law causes of action against Defendant Cyberonics, Inc.: 1) products liability-malfunction; 2) breach of warranty; 3) fraudulent misrepresentation; 4) violation of the New Jersey Consumer Fraud Act, N.J.S.A. § 56:8-19; and 5) negligence and negligent misrepresentation. Pending before the Court is Defendant's Motion for Summary Judgment (Docket No. 21) wherein Defendant argues that Plaintiffs' product liability and breach of warranty claims are preempted by the Medical Device Amendments (MDA), 21 U.S.C. § 360c et seq., to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq., and argues the additional claims are otherwise deficient. The Court heard oral argument on this matter on February 3, 2010. Plaintiffs' counsel acknowledged at argument that Counts Two through Five

are dismissed, thus the only claim pending before the Court is Count One-Products Liability. For the foregoing reasons, and for the reasons expressed in the record created this date, the Court grants the Motion for Summary Judgment.

I. BACKGROUND

Plaintiff Lisa Banner suffers from treatment resistant depression, or TRD. Persons suffering from TRD are those who "have not had adequate and/or sustained responses to multiple other antidepressant strategies." Def. br., Ex. C at 2. Because of Ms. Banner's failed response to other forms of treatment, she turned to VNS therapy on the recommendation of her treating physicians.

The VNS Therapy System is a Class III medical device approved by the United States Food & Drug Administration (FDA). The VNS Therapy System is manufactured by Defendant Cyberonics, Inc. The system involves the surgical implantation of a device (the generator), similar to a pacemaker, and a thin, flexible wire (the lead) that is supposed to send mild stimulation to the left vagus nerve. The lead extends from the generator to the neck where it attaches to the vagus nerve and delivers stimulation for thirty seconds every five minutes. The stimulation to the nerve is then delivered to the brain, which is intended to ameliorate the effects of TRD.

On February 27, 2007, Ms. Banner underwent surgical implantation of the VNS Therapy System at Cooper University Hospital in Camden, New Jersey. Ms. Banner experienced stimulation after the device was turned on and during the course of her treatment. However, Ms. Banner alleges that while the VNS Therapy System was implanted, she suffered exhaustion, severe pain in her chest and shoulder near the implant site, and severe pain in her neck and

behind her left ear. She alleges these pains were the result of the device's malfunctioning. Ms. Banner ultimately had the VNS Therapy System removed on June 16, 2008. As a result of Ms. Banner's use of the VNS Therapy System, her depression is no different now than it was before she underwent treatment.

After the device was removed from Ms. Banner, it was returned to Defendant Cyberonics for testing. Defendant's expert, Mario Garcia, analyzed both the generator and the leads and found that both were functioning as designed. Plaintiffs flatly refute the expert's conclusion and in fact offer the affidavit of Dr. Edward Tobe, Ms. Banner's treating psychiatrist, who testifies that the VNS Therapy System was malfunctioning.

Plaintiffs filed the original Complaint in this matter on February 12, 2008. After the Supreme Court decided Riegel v. Medtronic, Inc., 552 U.S. 312, 128 S. Ct. 999 (2008) on February 20, 2008, Plaintiffs filed the Amended Complaint on December 22, 2008. Defendant filed the present Motion for Summary Judgment on July 1, 2009, and all parties have submitted their papers responding to the Motion.

Notably, during the pendency of the present Motion, Judge Anita Brody rendered an opinion in a nearly identical case. See Williams v. Cyberonics, 654 F. Supp. 2d 301 (E.D. Pa. 2009).[1] Judge Brody granted Cyberonics's motion on all counts.

II. STANDARD

Summary judgment is appropriate where the court is satisfied that "there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed.

[1] The plaintiffs in Williams filed an appeal to the Third Circuit, see Civ. No. 06-5361, Docket No. 70 (E.D. Pa. Sept. 22, 2009); however, as of the date of this Opinion, no docket number had yet been assigned.

R. Civ. P. 56(c). A genuine issue of material fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).

"[T]he party moving for summary judgment under Fed.R.Civ.P. 56(c) bears the burden of demonstrating the absence of any genuine issues of material fact." Aman v. Cort Furniture Rental Corp., 85 F.3d 1074, 1080 (3d Cir. 1996). The moving party may satisfy its burden either by "produc[ing] evidence showing the absence of a genuine issue of material fact" or by "'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986). If the moving party satisfies its burden, the nonmoving party must respond by "set[ting] out specific facts showing a genuine issue for trial." Fed. R. Civ. P. 56(e)(2). "If the opposing party does not so respond, summary judgment should, if appropriate, be entered against that party." Id.

III. DISCUSSION

A. Premarket Approval

At the outset, it is important to discuss the process through which the VNS Therapy System came to the market. The VNS Therapy System is a Class III medical device that was subject to "premarket approval." Premarket approval is a "rigorous regime" wherein proposed devices are subject to thorough FDA review. See Riegel v. Medtronic, Inc., 552 U.S. 312, 128 S.

Ct. 999, 1004 (2008). A manufacturer of a Class III device subject to premarket approval must submit a multivolume application, which includes everything from studies and investigations to the manufacturing process. Id. The FDA spends an average of 1200 hours reviewing each premarket approval application, and it only grants approval if it finds "there is a 'reasonable assurance' of the device's 'safety and effectiveness[.]'" Id. (quoting 21 U.S.C. § 360e(d)). Once approved, a Class III medical device cannot undergo changes to design specifications, manufacturing processes, labeling, or any other attribute affecting safety or effectiveness without FDA approval. Id. at 1005 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). Also after approval, manufacturers are subject to on-going reporting requirements regarding the device. Id.

Within this context, the Court now turns to Count One of the Amended Complaint.

B. Count One–Products Liability

Count One of the Amended Complaint alleges that the "VNS Therapy device sold to plaintiff Lisa Banner was defective in manufacture, in that the device malfunctioned, and was thus incapable of providing plaintiff, as its end user, the intended use for which she purchased the device." Amd. Compl. at ¶ 29. Defendant alleges that Count One is preempted by the MDA. Def. br. at 8. Plaintiffs seemingly counter that the MDA does not preempt suits alleging a medical device malfunctioned; that is, alleging that a medical device was simply a "lemon." Pl. br. at 5-6.

The MDA contains an express preemption provision that states that "no State . . . may establish or continue in effect with respect to a device intended for human use any requirement–which is different from, or in addition to, any requirement applicable under the [FDCA] to the device . . . ." 21 U.S.C. § 360k(a)(1). A state requirement is preempted if two

conditions are met: 1) the Federal Government established requirements applicable to the device, and 2) the state-imposed requirement is "different from, or in addition to" the Federal requirements. Riegel, 128 S. Ct. at 1006. In the present dispute, the first condition is not in dispute as Plaintiffs acknowledge that the VNS Therapy System is subject to Federal Government requirements as a Class III medical device. See Pl. br. at 2 n.1.

The state-imposed requirement condition for preemption may be satisfied where a party seeks to impose liability based on a state tort cause of action for strict liability, negligence, or breach of implied warranty. See Riegel, 128 S. Ct. at 1009-10. The Riegel court reasoned that such claims are preempted because juries could determine a product was unreasonably dangerous based only on the patient before the court, without also seeing the benefit that such a product produced for other patients. Id. at 1008. The view of the entire picture and the calculation of the costs versus the benefits is a function entrusted to the FDA, not individual juries. See id. From this analysis, at least one court has thus concluded that "Riegel is loud and clear: if a manufacturer complies with the premarket approval, it gets a free pass on [products liability and implied breach of warranty] claims." Williams, 654 F. Supp. 2d at 306.

However, a tort action is only preempted if it imposes requirements that are "different from, or in addition to" Federal requirements. Riegel, 128 S. Ct. at 1011. This means that a claim survives a preemption challenge where it is based on a violation of FDA regulations. Id.; Williams, 654 F. Supp. 2d at 306 ("To avoid federal preemption, a plaintiff must make some showing that the medical device was not manufactured in accordance with FDA standards.").

At oral argument, Plaintiffs' counsel clarified their precise position in this dispute. Specifically counsel represented that it is Plaintiffs' belief that this particular VNS Therapy

System was manufactured according to FDA requirements; however, somehow an anomaly was introduced into the device. Under these circumstances, Plaintiffs argue that they can state a claim.

Plaintiffs' position is incorrect. The FDA approves the process by which a Class III device is manufactured, but it does not guarantee that every device manufactured in that process will work. Cf. Clark v. Medtronic, Inc., 572 F. Supp. 2d 1090, 1094 (D. Minn. 2008) ("Plaintiff is ultimately wrong when he assumes that premarket approval guarantees the device is completely safe."). Thus, if the FDA approves a manufacturing process and the defendant-manufacturer conforms with it, a device thereby produced that nevertheless does not function as intended does not give rise to liability. See Hughes v. Boston Scientific Corp., - - - F. Supp. 2d ---, 2009 WL 3817586, at *9 (S.D. Miss. 2009) ("[A] manufacturing defect claim would be preempted if the manufacturer followed the federally-approved manufacturing process for a device."); Wolicki-Gables v. Arrow Int'l, Inc., 641 F. Supp. 2d 1270, 1285 (M.D. Fla. 2009) (holding manufacturing defect claim preempted since a factfinder could find device unreasonably dangerous, "even if the manufacturer followed the FDA's manufacturing practices"). In effect, it is distinctly possible that the FDA-approved process introduces a margin of error wherein a properly manufactured device may nevertheless depart from its intended design. Under Riegel, state law cannot capture this departure and create liability for it because that would, in effect, require the manufacturer to use greater care than required by the FDA. Thus, Plaintiffs' argument that a device produced in compliance with the FDA-approved process may nevertheless give rise to a state law claim for product liability is incorrect.

Moreover, even if Plaintiffs were correct, they have failed to identify what if any defect

exists in this particular VNS Therapy System. Defendant has submitted an expert report stating that the device removed from Ms. Banner "is functioning per design requirements, by delivering consistent and accurate therapy that correspond to its programmed settings." Def. br., Ex. J at 2 (expert report of Mario Garcia). Plaintiffs' response is an affidavit from Dr. Tobe that he observed the device "malfunctioning" because it produced excessive fatigue in Ms. Banner and because it caused "unexpected severe pain."[2] Pl. br., Ex. 1 at ¶ 5.

However, nowhere in Dr. Tobe's affidavit or in Plaintiffs' brief is the Court directed to how this purported "malfunctioning" shows an anomaly. As just stated above, merely because a device does not work as intended is not proof that the device was not appropriately manufactured. In the wake of Riegel, once Defendants met their summary judgment burden by showing that the VNS Therapy System functioned properly, Plaintiffs had to do more than merely show that it did not work–they had to show a genuine issue of material fact exists as to whether the device's failure to work was the result of a deviation. Since no showing was made

[2] Dr. Tobe's expert conclusion that the VNS Therapy System was "malfunctioning" does not create a genuine issue of material fact as to whether the device actually was malfunctioning. Dr. Tobe conducted no testing whatsoever, as acknowledged at oral argument; instead he merely observed symptoms in Ms. Banner. Cf. Williams v. United States Army Corps. of Eng'rs, No. 06-834, 2007 WL 2261559, at *5 (D.N.J. Aug. 2, 2007) (striking expert report where plaintiff's expert conducted no testing on purportedly negligently designed berm system), aff'd, 321 Fed. Appx. 129 (3d Cir. 2009).

Additionally, as they seemingly did at oral argument, Plaintiffs cannot be heard to complain that they lacked the opportunity to engage in proper testing. Rule 56(f) exists for precisely the situation where a party feels that it cannot properly respond to a motion for summary judgment. Plaintiffs filed no affidavit here under Rule 56(f) attesting to the need for additional testing. The Court will not now entertain Plaintiffs' claims that they could not fully investigate this particular device.

here, Plaintiffs' product liability claim is preempted.[3]

Therefore, the Court grants Defendant's Motion for Summary Judgment as to Count One.

IV. CONCLUSION

For the foregoing reasons, Counts Two through Five are **DISMISSED** and Defendant's Motion for Summary Judgment is **GRANTED** as to Count One.

Date: 2/4/10

/s/ Robert B. Kugler
ROBERT B. KUGLER
United States District Judge

[3] Though not raised by Defendant, even if Plaintiffs had sufficiently identified a FDA regulation that was violated, it seems that Count One is not otherwise viable. All actions in New Jersey based on harm caused by a product must proceed under the New Jersey Product Liability Act (PLA), N.J.S.A. § 2A:58C-1 et seq. See Brown ex rel. Estate of Brown v. Phillip Morris, Inc., 228 F. Supp. 2d 506, 515 (D.N.J. 2002). Actions based on common law theories, such as strict liability or negligence, are barred. See id. at 516-17. Here, it appears that Plaintiffs' claim is brought under a common law theory of strict liability, and thus the claim cannot otherwise be sustained.